



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/426,038 | 10/25/1999 | JESPER VIND | 5579.210-US | 1334 |

25908 7590 05/15/2003

NOVOZYMES NORTH AMERICA, INC.
500 FIFTH AVENUE
SUITE 1600
NEW YORK, NY 10110

| EXAMINER |
|----------|
|----------|

PONNALURI, PADMASHRI

| ART UNIT | PAPER NUMBER |
|----------|--------------|
|----------|--------------|

1639

DATE MAILED: 05/15/2003

17

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/426,038

Applicant(s)

Vind

Examiner

Padmashri Ponnaluri

Art Unit

1639

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Feb 11, 2003
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-11, 13-18, 20-22, and 27-32 is/are pending in the application.
- 4a) Of the above, claim(s) 10, 22, and 27-29 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-9, 11, 13-18, 20, 21, and 30-32 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- *See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

Art Unit: 1639

DETAILED ACTION

1. The amendment D, and response filed on 2/11/03 have been considered and entered into the application.

2. Claim 19 has been canceled and claims 1, 3, 31 and 32 have been amended by the amendment D, filed on 2/11/03.

NOTE that the amendment to the independent claims 1 and 31 in the clean version of the claims is not the same as the Version with the Markings to show changes.

3. Claims 1-11, 13-^{18, 20-22}~~22~~, 27-32 are currently pending in this application.

4. Claims 22, 27-29 are withdrawn from further consideration by the examiner, 37 CAR 1.142(b) as being drawn to a non-elected invention. Election was made **without** traverse in Paper No. 7.

5. Claims 10 is withdrawn from further consideration by the examiner, 37 CAR 1.142(b) as being drawn to a non-elected species. Election was made **without** traverse in Paper No. 7.

6. This application contains claims 10, 22, 27-29 drawn to an invention nonelected without traverse in Paper No. 7. A complete reply to the final rejection must include cancellation of nonelected claims.

7. Claims 1-9, 11, 13-18, 20-21, 30-32 are currently being examined in this application.

8. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Art Unit: 1639

9. The rejections of claims under 35 U. S. C. § 112, second paragraph as 'incomplete or omitted essential subject matter' set forth in the previous office action mailed on has been maintained.

10. Claims 1-9, 11, 13-21, 30-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Christensen (WO 98/01470), Aleksenko et al (Molecular Microbiology (1996) 19 (3), 565-574) and Dalboge et al (Mol. Gen. Genet (1994) 243: 253-260.) for the reasons of record set forth in the previous office action mailed on 8/26/02.

11. Applicant's arguments filed on 2/11/03, regarding the art rejection of claims over Christensen, Alksenko and Dalboge et al have been fully considered but they are not persuasive.

Applicants argue that instant invention relates to method of screening of polynucleotide sequences of interest encoding a desired characteristics in filamentous fungal cells with a population of DNA vectors, and the vectors in the population that vary from other vectors in the population by carrying different version of the polynucleotide sequence of interest.

Applicants assert that 'screening variant library in a filamentous fungus using the vector-based expression system recited in the claims had not been disclosed or even suggested before the present invention.' Applicants assertions have been considered but are not persuasive, since the combined teachings of references teach the use of fungal vectors in screening a library of compounds (or proteins). A person skilled in the art at the time the invention was made would know how to make a library of vectors with each vector having variant sequences. And it would be obvious to one skilled in the art to make a library of vectors carrying or encoding different

Art Unit: 1639

sequences of a protein of interest, such that analogs of the protein would be identified by screening the library. In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 U. S. P. Q. 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 U. S. P. Q. 375 (Fed. Cir. 1986). Further more Christensen et al teach that fungal cells with alpha-amylase promoter regulating transcription factor and fungal host cells are used in the expression of the polypeptide of interest produced by said host. Christensen et al teach that the disclosed invention is used for enhancing the expression of a polypeptide of interest in filamentous fungi.

Applicants agrees with the examiner that Christensen teach cloning in yeast and filamentous fungi. And further argue that 'not many truly autonomously maintained plasmid systems had been described for filamentous fungi at the time of filing of this application. Applicants assert that the Aleksenko et al is co-authored by the inventors of this invention. Applicants assertions have been considered but are not persuasive, because the inventive entity of the present claimed invention is different from the list of co-authors of the reference.

Applicants argue and assert that 'screening a genomic library for a gene of interest, such as, is done for adC by Aleksenko et al and screening a library of variants of a polypeptide as defined in the present invention are two completely different tasks that require very different methodological approaches. The first is akin to finding the proverbial needle in the haystack by using a magnet, whereas the present invention is akin to looking for a number of particular sharp

Art Unit: 1639

needles in a stack of needles.' Applicants assertions have been considered but are not persuasive for the following reasons, the instant rejection is based on combined teachings of three references, applicants arguments are based on a single reference; and since the instant claimed method steps are incomplete and do not include any specific methods to identify the polynucleotide sequences of interest from the population of vectors; and it would be obvious to one skilled in the art at the time the invention was made to use the teachings of Christensen et al, Aleksenko et al and Dalboge et al in the method of screening a library of polynucleotides of interest in fungal cells such that enhanced expression of the polypeptide of interest is produced in the host cells.

Applicants arguments regarding screening of gene library is different from screening of variant library (i.e., finding the proverbial needle in the haystack by using a magnet, whereas the present invention is akin to looking for a number of particular sharp needles in a stack of needles) has been considered. In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., method of screening steps different for screening a variant library) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). If applicants believe that the claimed invention would differ in the method of screening a variant gene library, applicants are requested to include the method steps in the claimed method. Applicants arguments regarding screening would not read on instant claim 31

Art Unit: 1639

because it is drawn to a method of constructing a library of polynucleotide sequences of interest not to a method of screening for a polynucleotide of interest.

12. Applicant's arguments filed on 2/11/03 regarding the rejection of claims as 'incomplete' set forth in the office action mailed on 12/4/01 have been fully considered but they are not persuasive.

Applicants assert that the instant invention relates to "a method for screening a library of polynucleotide sequences of interest having or encoding a desired characteristic in a filamentous fungal cells", and how the transformants are selected depends on what the desired characteristics is in each embodiment of the invention. Any appropriate selection procedure is clearly applicable and is covered by the claims. Applicants assertions and arguments are not persuasive, because applicants arguments for the art rejections contradict the arguments for the 'incomplete claims'. Applicants supra argue that the instant claimed screening is different from the prior art known methods, and in response to the rejection of claims as 'incomplete' applicants state that any appropriate selection procedure is clearly applicable. And in the absence of the desired characteristics it is not clear which method steps are required to screen a library of variants. It seems in the claimed method the sequence of polynucleotide of interest and the desired characteristics are known (are required) such that a screening assay can be determined which would be useful in the claimed method. And the instant claims do not recite either polynucleotide of interest such that a library of vectors are created or desired characteristics such that a method

Art Unit: 1639

of screening can be determined. For the reasons of above applicants are requested to include specific method steps in the method of screening a variant library for a polynucleotide of interest.

13. No claims are allowed.

14. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CAR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CAR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to P. Ponnaluri whose telephone number is (703) 305-3884. The examiner is on ***Increased Flex Schedule*** and can normally be reached on Monday to Friday from 7.00 AM to 3.30 PM.

Art Unit: 1639

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang, can be reached on (703) 306-3217. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

P. Ponnaluri
Primary Examiner
Technology Center 1600
Art Unit 1639
11 May 2003


PADMASHRI PONNALURI
PRIMARY EXAMINER